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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/735,256 | 12/12/2003 | Stephen M. Strittmatter | A116 CON | 9794 |
| 1473 | 7590 | 09/29/2005 | EXAMINER | |
| FISH & NEAVE IP GROUP ROPES & GRAY LLP 1251 AVENUE OF THE AMERICAS FL C3 NEW YORK, NY 10020-1105 | | | WANG, CHANG YU | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1649 | |

DATE MAILED: 09/29/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/735,256

Applicant(s)

STRITTMATTER ET AL.

Examiner

Chang-Yu Wang

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 June 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10 and 22 is/are pending in the application.
- 4a) Of the above claim(s) 5 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4, 6-10 and 22 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Status of Application

1. Claims 1-30 are pending in the application. Claims 5, 11-21, and 23-30 are withdrawn from consideration as being drawn to a non-elected invention. Claims 1-4, 8-10 and 22 are under examination in this office action.

Election/Restrictions

2. Applicant's election with traverse of Group I and SEQ ID NO:2 in the reply filed on June 3, 2005 is acknowledged. The traversal is on the ground(s) that the inventions of Group I-VI are related with each other and there is no search burden for examiners. This is not found persuasive because each one of Groups I-VI is patentably distinct, in addition, each sequence in the application represents a distinct feature and may bind or mediate different molecules and functions. The products are distinct, each from the other, for the reasons set forth in the previous office action. They differ in both structure and function. The methods are similarly distinct because they require different reagents and have different goals. Additionally, the products require separate searches of separated databases, and the methods further require separate searches. Furthermore, separate classification is *prima facie* evidence of a search burden. It has further been stated that, should a product claim be found allowable, process claims that are commensurate in scope with what is allowed will be rejoined. With respect to Applicant's traversal of the restriction among species, the claims encompass many different sequences and variations thereof, which are not encompassed by a single

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search. As stated previously, rejoined will be considered when allowable subject matter is reached. In this instant case, claims 1, 2 and 7 are also under examination since SEQ ID NO:19 is a genus sequence encompassing the SEQ ID NO:2.

3. The requirement is still deemed proper and is therefore made FINAL.

Priority

4. Applicant's claim for the benefit of a prior-filed application under 35 U.S.C. 119(e) or under 35 U.S.C. 120, 121, or 365(c) is acknowledged. The priority date for this instant application is December 6, 2000.

Claim Objections

5. Claims 1-2, 5-10 and 22 are objected to as encompassing non-elected subject matter.

Claim Rejections - 35 USC § 101

6. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

7. Claims 1-4, 8-10, and 20 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility.

8. A specific and substantial utility is one that is particular to the subject matter claimed and that identifies a "real world" use for the claimed invention. See *Brenner v. Manson*, 148 U.S.P.Q. 689 (1966):

The basic quid pro quo contemplated by the Constitution and the Congress for granting a patent monopoly is the benefit derived by the public from an invention with substantial utility. . . . [u]nless and until a process is refined and developed to this point-where specific benefit exists in currently available form-there is insufficient justification for permitting an applicant to engross what may prove to be a broad field.

9. The specification fails to provide objective evidence of any activity for the encoded protein or to show that this protein even exists. While applicant lists a number of possible general uses for the polynucleotide and encoded protein on p. 6, these uses are not specific or substantial. The specification does not disclose any diseases or conditions known to be associated with or affected by the encoded polypeptide. Merely listing a number of possibilities is not sufficient to identify or confirm a "real world" context of use; clearly further research would be required to identify a disease in which the encoded protein is involved. Thus, further research is required to identify a disease for which it could be used, or a disease for which its presence would be diagnostic. Further, identification of molecules that interact with the encoded polypeptide (pp. 73-87) is useful only in research to determine the function of the protein itself: there is no "specific benefit in currently available form" to be derived from such studies. Applicant thus does not identify or confirm a "real world" context of use; clearly further research would be required to identify a disease or function associated with this protein and thus endow the encoding polynucleotides with a utility. See *Brenner v. Manson*, 383 U.S. 519, 535-36, 148 USPQ 689, 696 (1966), noting that "a patent is not a hunting license.

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It is not a reward for the search, but compensation for its successful conclusion." A patent is therefore not a license to experiment. See also the Revised Interim Utility Guidelines available at www.uspto.gov.

10. The claimed invention also lacks a well-established utility. A well-established utility is a specific, substantial, and credible utility that is well known, immediately apparent, or implied by the specification's disclosure of the properties of a material. Applicant states (p. 7 and figure 1) that the polynucleotide is homologous to a known NOGO receptor.

11. The specification teaches that SEQ ID NO:2 is a homolog of Nogo receptor-1. However, the specification does not specify the function of SEQ ID NO:2. It has been shown that different homologs of receptors even binding to the same ligand may function differently. Although they share similar structure motifs, even share more than 80% identity, they still can function totally oppositely. The most obvious example is the estrogen receptor. Both estrogen receptor-alpha and -beta bind to estrogen and share highly homology (95% amino acid identity for DNA-binding domain and 55% amino acid identity for ligand-binding domain). However, estrogen receptor-beta functions as a dominant negative molecule in cell proliferation whereas estrogen receptor-alpha functions in promoting cell proliferation. See Gustafsson, J. A.. Eur J Cancer. 2000 Sep;36 Suppl 4:S16. Another example is the same ligand binding to different receptors to execute different biological functions. p75NTR, which is a receptor binding to

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neurotrophin NGF, activates a signal transduction cascades for neuronal apoptosis.

However, Trk-A receptor, another NGF binding receptor, functions in promoting neuronal survival. Although both p75NTR and Trk-A receptor bind to NGF, they function in a very different manner in neuronal survival. See Nykjaer et al. Curr Opin Neurobiol. 2005 Feb; 15:49-57.

12. Thus, in this instant application, Applicant fails to specify or establish the function or utility of SEQ ID NO:2 even though SEQ ID NO:2 is a homolog of Nogo receptor-1. For the reasons given above, Applicant has not specified either a specific and substantial asserted utility or a well established utility for the current invention.

Claim Rejections - 35 USC § 112

13. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

14. Claims 1-4, 8-10, and 20 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

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15. Claims 1-3, 8-10, and 22 are further rejected under 35 U.S.C. 112, first paragraph, because the specification, were it enabling for a polynucleotide comprising SEQ ID NO: 2, would still not reasonably provide enablement for variants and sequences comprising fragments of the polynucleotide. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in the scope with these claims.

16. "There are many factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is 'undue'. These factors include, but are not limited to:

(A) The breadth of the claims;

(B) The nature of the invention;

(C) The state of the prior art;

(D) The level of one of ordinary skill;

(E) The level of predictability in the art;

(F) The amount of direction provided by the inventor;

(G) The existence of working examples; and

(H) The quantity of experimentation needed to make or use the invention based on the content of the disclosure.

In re Wands, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988)". See MPEP § 2164.01.

17. The claims are drawn to polynucleotides and a method of making peptides, which encompass variants and sequences comprising fragments that could vary widely in structure and in function. There are no required common regions and there is no guidance as to what could be changed and what could not be changed to preserve any common characteristics. There is no particular activity required. The specification does not provide guidance of how to make and use this broad genus. Because no limitation in the breadth of the claims, the unpredictability of the invention, and the lack of knowledge of function for each sequence, it would require undue experiments to use the invention commensurate in the scope with these claims.

18. Claims 1-3, 8-10, and 22 are also rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. These claims are drawn to a genus, i.e. polynucleotides of limited homology to SEQ ID NO: 2. Applicant has not disclosed sufficient species for the broad genus of any polynucleotide related to SEQ ID NO: 2.

19. A description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus or of a recitation of structural features common to members of the genus, which features constitute a substantial portion of the genus. *Regents of the*

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University of California v. Eli Lilly & Co., 119 F3d 1559, 1569, 43 USPQ2d 1398, 1406 (Fed. Cir. 1997). The instant specification fails to provide sufficient descriptive information, such as definitive structural or functional features of the claimed genus of polynucleotides. While a generic sequence is provided, there is merely a set of common properties: there is no description of the conserved regions which are critical to the function of the genus claimed. There is no description of the sites at which variability may be tolerated and there is no information regarding the relation of structure to function. Structural features that could distinguish the compounds in the genus from other compounds are missing from the disclosure. Furthermore, the prior art does not provide compensatory structural or correlative teachings sufficient to enable one of skill to isolate and identify the polynucleotides encompassed: there is no guidance in the art as to what the defining characteristics of NOGO receptors might be. Thus, no identifying characteristics or properties of the instant polynucleotides are provided such that one of skill would be able to predictably identify the encompassed molecules as being identical to those instantly claimed.

NO CLAIM IS ALLOWED

20. Any inquiry of a general nature or relating to the status of this general application should be directed to the Group receptionist whose telephone number is (571) 272-1600.

21. Papers relating to this application may be submitted to Technology Center 1600, Group 1649 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). Should applicant wish to FAX a response, the current FAX number for Group 1600 is (571) 273-8300.

22. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chang-Yu Wang, Ph.D. whose telephone number is (571) 272-4521. The examiner can normally be reached on Monday-Friday from 8:30 AM to 5:30 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet Andres, Ph.D., can be reached at (571) 272-0867.

23. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

CYW
September 9, 2005


JANET L. ANDRES
SUPERVISORY PATENT EXAMINER